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10/002,540	11/13/2001	Steven C. Quay	ATOS-0040	3267

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Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,540

Applicant(s)

QUAY, STEVEN

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 and 52-54 is/are rejected.
- 7) ☒ Claim(s) 50 and 51 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The instant application contains a specific reference to the prior provisional applications; however, the specific reference is not provided in the first sentence of the specification.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

3. Claim 6 is objected to because of the following informalities: in line 2, "can" apparently should read --is adapted to--. Appropriate correction is required.
4. Claim 11 is objected to because of the following informalities:
 - a. In line 3, "and/or to" apparently should read --and--.

b. In line 4, "or" apparently should read --of--.

Appropriate correction is required.

5. Claim 28 is objected to because of the following informalities: in line 3, "fluid" apparently should be deleted in order to maintain consistent terminology for the limitation. Appropriate correction is required.

6. Claim 30 is objected to because of the following informalities:

a. In line 2, "closure" (second occurrence) apparently should read --closing-- and --member-- apparently should be inserted following "reservoir" (second occurrence).

b. In line 4, --member-- apparently should be inserted following "reservoir".

Appropriate correction is required.

7. Claim 32 is objected to because of the following informalities:

a. In line 3, --member-- apparently should be inserted following "reservoir" (first occurrence).

b. In line 5, "the air port(s)" apparently should read --the one or more air ports--.

Appropriate correction is required.

8. Claim 34 is objected to because of the following informalities:

In line 5, "the air port(s)" apparently should read --the one or more air ports-- and --member-- apparently should be inserted following "reservoir".

Appropriate correction is required.

9. Claim 35 is objected to because of the following informalities:

In line 5, --member-- apparently should be inserted following “reservoir”.

Appropriate correction is required.

10. Claim 37 is objected to because of the following informalities:

In line 5, “the air port(s)” apparently should read --the one or more air ports--.

Appropriate correction is required.

11. Claim 38 is objected to because of the following informalities:

In lines 3 and 6, --member-- apparently should be inserted following “reservoir”.

Appropriate correction is required.

12. Claim 40 is objected to because of the following informalities:

a. In line 5, “can” apparently should read --is adapted to--.

b. In line 5, “the air port(s)” apparently should read --the one or more air ports--.

Appropriate correction is required.

13. Claim 42 is objected to because of the following informalities:

In line 3, --breast-- apparently should be inserted before “engaging”.

Appropriate correction is required.

14. Claim 43 is objected to because of the following informalities:

In lines 3 and 4, --member-- apparently should be inserted following “reservoir”.

Appropriate correction is required.

15. Claim 45 is objected to because of the following informalities:

In line 4, --breast-- apparently should be inserted before “engaging”.

Appropriate correction is required.

16. Claim 47 is objected to because of the following informalities:

In line 3, --means-- apparently should be inserted following “pump”.

Appropriate correction is required.

17. Claim 50 is objected to because of the following informalities:

In line 2, --vacuum-- apparently should be inserted before “pump” (second occurrence).

Appropriate correction is required.

18. Claim 51 is objected to because of the following informalities:

In line 1, --vacuum-- apparently should be inserted before “pump”.

Appropriate correction is required.

19. Claim 52 is objected to because of the following informalities:

In line 2, "actuation" apparently should read --actuating--.

Appropriate correction is required.

20. Claim 54 is objected to because of the following informalities:

In lines 3 and 4, --member-- apparently should be inserted following "reservoir".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 3, 4, 7, 10, 12-45, 47, 48 and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3, 4, 7, 12-15, 18, 19, 24, 28 and 37, the excessive use of alternative language renders the claims indefinite. The excessive use of the word "or" in a single claim makes the metes and bounds of the claimed invention unclear.

Regarding claim 3, the phrase "may be" in line 3 renders the claim indefinite. It is unclear whether the plurality of components are disassembled or if the plurality of components are merely adapted to be disassembled.

Regarding claim 4, the claim language renders the claim indefinite as it is unclear whether the “separate breast engaging member” recited in line 2 is the same breast engaging member recited in claim 1 or if the “separate breast engaging member” is a distinct element.

Regarding claim 10, the inconsistent terminology used to define the limitation “the pad or sheet” in line 1 renders the claim indefinite. It is unclear whether there is only one pad or sheet or if there can be more.

Regarding claims 13-18, 21, 41 and 42, due to the alternative language used in claim 12, the device does not necessarily include a housing although the housing is positively recited in claims 13-18.

Claim 18 recites the limitation “the casing member wall” in line 5. There is insufficient antecedent basis for this limitation in the claim. There is no casing member wall recited in the claims prior to this recitation.

Regarding claim 23, the use of alternative language renders the claim indefinite. The ambiguity involves the word “or” recited in line 3. It is unclear how the reservoir member functions as both a conduit and a receptacle or a secondary collection medium.

Regarding claim 24, it is unclear from the claim language in line 4 what is or may be coupled with the breast engaging member.

Regarding claim 25, it is unclear whether the “primary solid phase sample collection medium” recited in lines 1-2 is the same solid phase sample collection medium recited in claim 1 or if the “primary solid phase sample collection medium” is a distinct element.

Regarding claim 35, the phrase “may be” in line 2 renders the claim indefinite. It is unclear whether the tab or sticker is applied to the air port or if the tab or sticker is merely adapted to be applied to the air port.

Further regarding claim 35, the inconsistent terminology used to define the limitation “the air port” in lines 3 and 4 renders the claim indefinite. It is unclear whether there is only one air port or if there can be more.

Regarding claim 37, the phrase “can be” in line 3 renders the claim indefinite. It is unclear whether the tab or sticker is repositioned or manipulated or if the tab or sticker is merely adapted to be repositioned or manipulated.

Claim 38 recites the limitations “the first, closure-forming surface” in lines 4 and 6 and “the second, labeling surface” in lines 5 and 7. There is insufficient antecedent basis for these limitations in the claim. These limitations are originally set forth in claim 35 and not claims 37 or 32.

Further regarding claim 38, the inconsistent terminology used to define the limitation “the air port” in lines 3 and 6-7 renders the claim indefinite. It is unclear whether there is only one air port or if there can be more.

Regarding claim 42, the phrase “can be” in line 3 renders the claim indefinite. It is unclear whether or not the engaging member is directly coupled to the fluid reservoir member.

Claim 45 recites the limitation “the sample collection housing” in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no sample collection housing recited in claims 1 or 45 prior to this recitation.

Further regarding claim 45, it is unclear whether the limitation “the pump” as recited in line 4 is intended to refer to the “breast pump” or the “vacuum pump means”.

Claim 47 recites the limitation “the sample collection housing” in line 3. There is insufficient antecedent basis for this limitation in the claim. There is no sample collection housing recited in claims 1 or 47 prior to this recitation.

Claim 48 recites the limitation “the outer casing member of the sample collection housing” in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no outer casing member of the sample collection housing recited in the claims prior to this recitation.

Claims 52 and 53 recite the limitation “the sample collection housing” in line 4. There is insufficient antecedent basis for this limitation in the claims. There is no sample collection housing recited in claims 1 or 52 prior to these recitations.

Regarding claim 54, it is unclear whether the limitation “the housing” as recited in line 2 is intended to refer to the “vacuum pump housing” or the “sample collection housing”.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

24. Claims 1-13, 45 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Quay et al. (521). Quay et al. teach a sample collection device including a breast engaging member constructed of a non-porous material sized and dimensioned to receive at least a nipple portion of a breast of said patient and form a suction seal therewith; a solid phase sample collection medium in fluid connection with said breast engaging member for receiving a sample of expressed breast fluid; and vacuum pump means in gaseous connection with said breast engaging member for generating negative pressure through the breast engaging member to facilitate breast fluid expression. The sample collection device is a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand. The solid phase sample collection medium is selected from the group consisting of microscopic glass slides, capillary tubes, collection tubes, columns, micro-columns, wells, plates, membranes, filters, resins, inorganic matrices, beads, resins, particulate chromatographic media, plastic microparticles, latex particles, coated tubes, coated templates, coated beads, coated matrices, or a combination thereof. The hand-held breast pump is a modular device formed of a plurality of components that are joined or securable in fixed structural interconnection with one another and may be partially or completely disassembled. The solid phase sample collection medium is supported by a support member removably mounted in fluid connection with said breast engaging member. The support member is provided as a removable cassette that can be inserted within said breast engaging member to be removably mounted in fluid connection therewith. The support member supports one or more pads or sheets of absorbent or adsorbent material. The solid phase sample collection medium may be a nitrocellulose membrane having a pore size

selected to effectively retain whole cells from expressed breast fluid on a surface of the membrane. The pad or sheet is a modified membrane or filter having perforations or slits that disrupt the planar surface of the membrane or filter to facilitate air passage therethrough. The support member incorporates one or more air channels that pass through a body of the support member. A fluid-retaining recess, well or reservoir is connected with the support member or a sample collection housing member of the hand-held pump device. The solid phase sample collection medium is adjustably mounted relative to the sample collection housing so that the solid phase collection medium can be controllably moved closer to, or farther away from, a base of the engaging member of the pump during use. A reciprocating mechanism adjustably moves the solid phase sample collection medium in closer, or more distant, proximity to the nipple.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 USC 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

25. Claims 1-13, 45 and 46 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Quay et al. ('521), as discussed hereinabove, teach all of the limitations of the claims. The Quay et al. reference has a common inventor with the instant application, but the instant application eliminates a second inventor while claiming the same subject matter.

26. Claims 1-4, 12, 13 and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Covington et al. ('513). Covington et al. teach an intraductal breast fluid aspiration device **20**. The device includes a breast engaging member **24** constructed of a non-porous material sized and dimensioned to receive at least a nipple portion of a breast of said patient and form a suction seal therewith; a solid phase sample collection medium (col. 4, lines 16-22) in fluid connection with said breast engaging member for receiving a sample of expressed breast fluid; and vacuum pump means **22** in gaseous connection with said breast engaging member for generating negative pressure through the breast engaging member to facilitate breast fluid expression. The sample collection device is a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand. The solid phase sample collection medium is a membrane (col. 4, lines 16-22). The hand-held breast pump is a modular device formed of a plurality of components that are joined or securable in fixed structural interconnection with one another and may be partially or completely disassembled (col. 12, lines 44-46). A fluid-retaining reservoir is connected with the support member or a sample collection housing member of the hand-held pump device (col. 4, lines 14-16). A compact vacuum pump housing integrates the vacuum pump with the sample collection housing and a vacuum pump actuating mechanism **25** is connected to a vacuum pump housing of the device.

Double Patenting

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

28. Claims 1-8, 11, 12, 45 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-9 and 11 of U.S. Patent No. 6,287,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent. The claims of the patent recite all of the limitations of the claims of the instant application, and further recite additional limitations that are not recited in the instant application. The limitations of claims 1, 2 and 8 of the instant application are recited in claim 1 of the patent. The limitations of claims 3 and 4 of the instant application are recited in claim 2 of the patent. The limitations of claim 5 of the instant application are recited in claim 3 of the patent. The limitations of claim 6 of the instant application are recited in claim 9 of the patent. The limitations of claim 7 of the instant application are recited in claim 5 of the patent. The limitations of claim 11 of the instant application are recited in claim 8 of the patent. The limitations of claim 12 of the instant application are recited in claims 6 and 7 of the patent. The limitations of claims 45 and 46 of the instant application are recited in claim 11 of the patent.

Since the claims of the patent can be said to “anticipate” the broader claims of the instant application, the claims are not patentably distinct.

Allowable Subject Matter

29. Claims 50 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

30. Claims 14-44 and 52-54 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

31. The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teach or suggest a sample collection device as recited by Applicant in claim 1 and further including a removable fluid reservoir member in the sample collection housing; a vacuum pump actuating mechanism including an actuating lever pivotally connected to a pump housing; or a vacuum pump means including a flexible diaphragm member and pump actuation means to draw the diaphragm member away from a primary vacuum chamber connected with a sample collection housing.

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Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Covington ('660) teaches methods and apparatus for measuring factors in mammary fluids. Aida et al. ('957) teach a breast pump having a pressure adjusting mechanism. Larsson ('229) teaches a breast pump having a valve that controls a path to a milk container. Sartorius ('801) teaches a method and apparatus for detecting cancer of the breast.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9323 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Examiner
Art Unit 3736

CAM
March 10, 2003